

# **PUMPING FLUID DELIVERY SYSTEMS AND METHODS USING FORCE APPLICATION ASSEMBLY**

## **CROSS REFERENCE TO RELATED APPLICATIONS**

**[0001]** This application is a continuation of U.S. patent application Ser. No. 13/089,927, filed Apr. 19, 2011, now U.S. Pat. No. 10,709,838, issued Jul. 14, 2020 and entitled “Pumping Fluid Delivery Systems and Methods Using Force Application Assembly” (Attorney Docket No. 179), which is a continuation of U.S. patent application Ser. No. 11/704,896, filed Feb. 9, 2007, now Publication No. US-2007-0219496, published Sep. 20, 2007 and entitled “Pumping Fluid Delivery Systems and Methods Using Force Application Assembly” (Attorney Docket No. 1062/E71) the entire disclosure of which is incorporated herein by reference.

**[0002]** U.S. patent application Ser. No. 11/704,896, also claims priority from the following U.S. Provisional patent applications, all of which are hereby incorporated herein by reference in their entireties:

**[0003]** Provisional Application Ser. No. 60/772,313, filed Feb. 9, 2006 and entitled “Portable Injection System” (Attorney Docket No. 1062/E42);

**[0004]** Provisional Application Ser. No. 60/789,243, filed Apr. 5, 2006 and entitled “Method of Volume Measurement for Flow Control” (Attorney Docket No. 1062/E53); and

**[0005]** Provisional Application Ser. No. 60/793,188, filed Apr. 19, 2006 and entitled “Portable Injection and Adhesive System” Docket No. 1062/E46).

**[0006]** This application may also be related to one or more of the following U.S. patent applications filed on even date herewith, all of which are hereby incorporated herein by reference in their entireties:

**[0007]** U.S. patent application Ser. No. 11/704,899, filed Feb. 9, 2007, now U.S. Publication No. US-2007-0228071, published Oct. 4, 2007 and entitled “Fluid Delivery Systems and Methods” (Attorney Docket No. 1062/E70);

**[0008]** U.S. patent application Ser. No. 11/704,886, filed Feb. 9, 2007, now U.S. Publication No. US-2007-0219480, published Sep. 20, 2007 and entitled “Patch-Sized Fluid Delivery Systems and Methods” (Attorney Docket No. 1062/E72);

**[0009]** U.S. patent application Ser. No. 11/704,897, filed Feb. 9, 2007, now Publication No. US-2007-0219597, published Sep. 20, 2007 and entitled “Adhesive and Peripheral Systems and Methods for Medical Devices” (Attorney Docket No. 1062/E73); and

**[0010]** Provisional Application Ser. No. 60/889,007, filed Feb. 9, 2007 and entitled “Two-Stage Transcutaneous Insertor” (Attorney Docket No. 1062/E74).

## **FIELD OF THE INVENTION**

**[0011]** This application relates generally to pumping fluid delivery systems and methods using force application assembly.

## **BACKGROUND**

**[0012]** Many potentially valuable medicines or compounds, including biologicals, are not orally active due to poor absorption, hepatic metabolism or other pharmacokinetic factors. Additionally, some therapeutic compounds,

although they can be orally absorbed, are sometimes required to be administered so often it is difficult for a patient to maintain the desired schedule. In these cases, parenteral delivery is often employed or could be employed.

**[0013]** Effective parenteral routes of drug delivery, as well as other fluids and compounds, such as subcutaneous injection, intramuscular injection, and intravenous (IV) administration include puncture of the skin with a needle or stylet. Insulin is an example of a therapeutic fluid that is self-injected by millions of diabetic patients. Users of parenterally delivered drugs would benefit from a wearable device that would automatically deliver needed drugs/compounds over a period of time.

**[0014]** To this end, there have been efforts to design portable devices for the controlled release of therapeutics. Such devices are known to have a reservoir such as a cartridge, syringe, or bag, and to be electronically controlled. These devices suffer from a number of drawbacks including the malfunction rate. Reducing the size, weight and cost of these devices is also an ongoing challenge.

## **SUMMARY OF THE INVENTION**

**[0015]** In one embodiment, the present invention provides a method of dispensing a therapeutic fluid from a line. The method includes providing an inlet line connectable to an upstream fluid source. The inlet line is in downstream fluid communication with a pumping chamber. The pumping chamber has a pump outlet. The method also includes actuating a force application assembly so as to restrict retrograde flow of fluid through the inlet while pressurizing the pumping chamber to urge flow through the pump outlet.

**[0016]** In a related embodiment, actuating the force application assembly includes using travel of the force application assembly during a work stroke to restrict retrograde flow and to pressurize the pumping chamber in a single mechanical action. In a further related embodiment, a given degree of travel of the force actuation assembly restricts retrograde flow, and a greater degree of travel pressurizes the pumping chamber.

**[0017]** In a further related embodiment, actuating the force application assembly includes restricting retrograde flow toward the fluid source by occluding the inlet line. Alternatively or in addition, the method also includes preventing reverse flow of fluid from a dispensing chamber into the pumping chamber by using a passive valve placed therebetween.

**[0018]** Optionally actuating the force application assembly includes using a shape-memory actuator. Also optionally, using the shape-memory actuator includes inducing a phase change in a shape memory wire to transmit a force around a pulley to the force application assembly.

**[0019]** In a further embodiment, the method further includes measuring a parameter related to flow through the line; and adjusting operation of the pump based on the measured parameter. Optionally measuring the parameter related to flow through the line includes determining a change in volume of a resilient chamber disposed downstream of the pumping chamber. Optionally, measuring the parameter includes using acoustic volume measurement.

**[0020]** In a further embodiment, a tortuous flow-impedance located downstream of the resilient chamber supplies a fluid impedance sufficient to cause the resilient chamber to expand in response to pumping.